REMARKS

The withdrawal of all prior rejections is appreciated.

The rejection of claims 53 and 59 as being anticipated by Prosl et al (U.S. Patent No. 5,989,206) is traversed.

The rejection does not state a prima facie case for anticipation because it does not clearly describe now the disclosure in Prosl et al is applied to anticipate all of the elements of claims 53 and 59. There is no statement in the rejection as to what portions of Prosl et al discloses inserting a withdrawal needle and later an withdrawal catheter in a surface peripheral vein. Further, there is no anticipation because in Prosl et al do not disclose the following claim elements:

- inserting a withdrawal needle in a surface peripheral vein in an extremity of the patient;
- determining that an insufficient amount of blood is withdrawn through the needle by determining that the withdrawn blood is below a predetermined threshold amount of blood;
- in response to the determination, replacing the needle with a blood withdrawal catheter inserted in the surface peripheral vein, and maneuvering the catheter through the vein to position a tip of the catheter in one of a large vein, great vein or vena cava to access a reservoir of blood for continuous blood withdrawal.

The invention is directed to a method to withdraw blood from a peripheral catheter having an extended length to reach a large or great vein or the vena cava and to a method in which an attempt to withdraw blood is first made by a withdrawal needle in a peripheral vein and thereafter blood is withdrawn by inserting an extended catheter into a peripheral vein to access a reservoir of blood in the large or great vein or vena cava. The claimed invention addresses a problem that arises in ultrafiltration when blood withdrawal through a peripheral vein is insufficient to provide the blood flow, e.g., less than 40 ml/min, for the intended ultrafiltration treatment. The invention solves this problem by substituting a mid-length catheter for a short catheter needle. The mid-length catheter is introduced into a peripheral vein and extends through the veneous system to a large vein or other reservoir of blood in the patient.

Prosl et al disclose a "subcutaneous port and catheter assembly" for dialysis. Prosl, Abstract. The subcutaneous port and catheter assembly disclosed in Prosl et al provides a central access directly to a large vein, such as the jugular vein. There is no disclosure in Prosl et al of inserting a catheter in a surface peripheral vein and advancing the catheter to a larger vein. Prosl et al (Fig. 2) discloses a PTFE graft implanted in a patient's arm to provide access for fistula needles. Prosl et al describe many disadvantages of PTFE grafts and do not suggest that a catheter may be inserted in a PTFE graft and advanced through peripheral veins to a large vein. Prosl et al teach away from the claimed invention by disclosing a central access subcutaneous port and catheter assembly rather

than the surface peripheral vein access for a catheter that is claimed in the rejected claims.

The rejection of claims 54 to 58 and 60 for obviousness based on Prosl et al is traversed for the reasons stated above regarding independent claim 53.

The claimed invention would not have been obvious in view of the blood treatment device shown in Prosl. Prosl et al do not recognize the problem addressed by the inventor or suggest a solution to that problem. Prosl et al provide no suggestion to form the claimed invention and would not render the invention to have been obvious.

Prosl et al disclose a subcutaneous port and catheter assembly to access a central vein. Central venous access lines tend to be much too large for peripheral vein access. It would be counter to such traditional central access blood treatment systems to rely on a narrow peripheral blood catheter to withdraw blood. Prosl et al, at col. 6, lns. 15-19, state a disadvantage of the peripheral access PTFE graft is it provides too little blood. It would have been counter-intuitive to use a narrow peripheral catheter tube to access a central vein. Prosl et al do not teach a method in which blood is first withdrawn from a surface peripheral vein, in which a determination is made that the amount of blood through the surface needle is inadequate and thereafter a catheter is inserted into a peripheral vein of the patient to "one of a large vein, great vein or vena cava to access a reservoir of blood for continuous blood withdrawal."

Secondary Consideration: Invention Recognized by Other As An Advancement In the Art

Jaski et al is a recognition of the invention in a peer reviewed article. As such, Jaski et al is a secondary consideration of non-obviousness. Jaski et al describes the same ultrafiltration system that is the subject of this application, and is evidence of non-obviousness. The ultrafiltration system described in this application, i.e., made by CHF Solutions, is the subject of the Jaski et al article.[1] [Jaski Article, p. 228.]

Jaski et al is secondary evidence of non-obvious because it shows that "conventional systems" where cumbersome and favorably discusses ultrafiltration using peripheral vein access. Jaski et al is an article published by the Journal of Cardiac Failure and is a peer-reviewed article. The statements in the article regarding the benefits of peripheral access for ultrafiltration and the difficulties with the prior art central access support a finding that the claimed invention was not obvious. The recognition from peers in the art given to the invention in the Jaski et al is a secondary consideration of non-obviousness. *United States v. Adams et al.*, 148 USPQ 479, 484 (U.S. 1966)("Several of the same experts subsequently recognized the significance of the Adams invention.").

Jaski et al describes the use of a mid-length catheter ("25 or 35 cm") with the ultrafiltration system and, thus, is directly relevant to the subject matter claimed in this application. Jaski Article, p. 228. Jaski et al state that: "[t]o our knowledge, this is the first clinical report of rapid removal of extracellular and intravascular fluid volume excess via ultrafiltration without use of a central venous catheter," ("Discussion" heading at page 229); "[r]apid removal of extracellular and intravascular fluid volume excess can

[1] Jaski et al was prepared with the technical and financial support of the owner of this application.

be safely achieved via peripherally inserted ultrafiltration without the need for central venous catheter placement" ("Conclusions" heading of the Abstract at page 227); and "[u]se of conventional systems, however, may be cumbersome, requiring physician placement of double-lumen central venous catheter …" ("Background" heading of the Abstract at page 227). Accordingly, Jaski et al teach that central venous catheters are conventional for ultrafiltration, that peripheral vein access with a mid-length catheter successfully treated patients suffering from circulatory volume overload, and that the use of a mid-length catheter inserted through a peripheral vein was less cumbersome than the prior art technique of central venous catheter access.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed

herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Jeffry Nelson/
Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100